REMARKS

Claims 1, 5-10, 12, 17-26, and 32-38 are pending.

Claims 1, 5-10, 12, and 35-38 are withdrawn.

Claims 2-4 and 27-31 are cancelled, without prejudice, and with the reservation of the right to file said claims and related subject matter in continuing and/or divisional applications.

Claims 17-26 and 32-34 are under examination.

Claims 1, 12, 17-19, 21-25, and 35 are amended herein.

No new matter is added.

Claim of Priority under 35 U.S.C. §120

Applicants respectfully request that the Examiner acknowledge that all of the claims in the present application have an effective filing date of September 16, 2002, which is the filing date of the priority document United States Provisional Application No. 60/410,818.

Rejections of Claims and Traversal Thereof

In the August 10, 2010 Office Action,

claims 17-26 and 32-34 were rejected under 35 U.S.C. §112, second paragraph;

claims 17-26 and 32-33 were rejected under 35 U.S.C. §102(e)(1) as being anticipated by Kyle (US 2004/0081638) (hereinafter Kyle '638);

claims 17-26 and 32-33 were rejected under 35 U.S.C. §102(e)(2) as being anticipated by Sayre, *et al.* (US Patent No. 7,410,637) (hereinafter Sayre); and

claim 34 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kyle '638 or Sayre in view of Nakamura *et al.*, JP 200354490 (abstract) (hereinafter Nakamura).

The above-defined rejections are hereby traversed, and reconsideration of the patentability of the pending claims is requested, in light of the ensuing remarks.

Rejections under 35 U.S.C. §112, second paragraph

Claims 18, 19, and 21-24 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite because of an antecedent basis issue concerning the phrase: "the recombinant viral protein or peptide." These claims have been amended to recite "the recombinant viral protein or the recombinant viral peptide" based on the Examiner's suggestion. Claim 17 has been similarly amended to maintain consistency between the independent and dependent claims. Further, withdrawn method claims have been similarly amended such that upon allowance of the product claims, the method claims will also be allowed.

The Examiner's rejection of claims 18-26 and 32-34 under 35 U.S.C. §112, second paragraph, in paragraph 14 of the August 10, 2010 Office Action is unclear. The rejection refers back to paragraph 22(j) of the May 14, 2009 Office Action, which states that "Claims 18-26 and 32-34, which depend directly or indirectly from claim 17, are also rejected as being indefinite because of the indefiniteness identified above in the base claim." In the May 14, 2009 Office Action, claim 17 was rejected under 35 U.S.C. §112, second paragraph, for four different reasons. Without clarification, Applicants do not know which of the four, or possibly more, reasons the Examiner found to reject claim 17 are being applied to claims 18-26 and 32-34. Nevertheless, Applicants believe that each reason for rejecting claim 17 has been addressed either herein or in a previous response and request withdrawal of any rejections of dependent claims 18-26 and 32-34 under 35 U.S.C. §112, second paragraph.

Thus, Applicants have addressed all §112 rejections and request the withdrawal of same.

Rejections under 35 U.S.C. §102(e)

1. Claims 17-26 and 32-33 were rejected under 35 U.S.C. §102(e)(1) as being anticipated by Kyle '638. It should be noted that Kyle '638 is a CIP of PCT International Application No. PCT/US02/27198, filed on August 27, 2002, which in turn claims priority to U.S. Provisional Application No. 60/314,637,

filed on August 27, 2001 (Copies of both applications are included in Appendix A). Reviewing both the provisional application and the subsequently filed PCT application, it is evident that neither of these documents disclose, teach, or suggest the presently claimed invention. As such, the Kyle '638 U.S. publication is only entitled to the October 14, 2003 filing date. Applicants submit that the present invention has an effective filing date of September 16, 2002, which is before the effective filing date of Kyle '638. As such this reference is not competent prior art and this rejection should be withdrawn.

2. Claims 17-26 and 32-33 were rejected under 35 U.S.C. §102(e)(2) as being anticipated by Sayre. Applicants submit that this reference is not anticipatory and does not defeat the patentability of the presently claimed invention.

Applicants' claim 17 recites the following:

> 17. A feed for an animal comprising one or more expressed recombinant viral protein or recombinant viral peptide from white spot syndrome virus (WSSV) or Taura Syndrome Virus (TSV), wherein the recombinant viral protein or the recombinant viral peptide binds to and blocks viral receptors needed for WSSV or TSV infection in the gut of the animal, wherein the recombinant viral protein or the recombinant viral peptide is selected from the group consisting of VP24, VP28, VP26, VP19, and TSV capsid protein.

Anticipation under 35 U.S.C. § 102 requires the presence, in a single reference, of each and every element of the claimed invention, **arranged as in the claim.** *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984). The Sayre reference does not meet this standard.

Sayre teaches the induction of an immune response and never discloses, teaches, or suggests the binding or blocking of receptors in the gut of an animal consuming the expressed recombinant proteins. According to the Office:

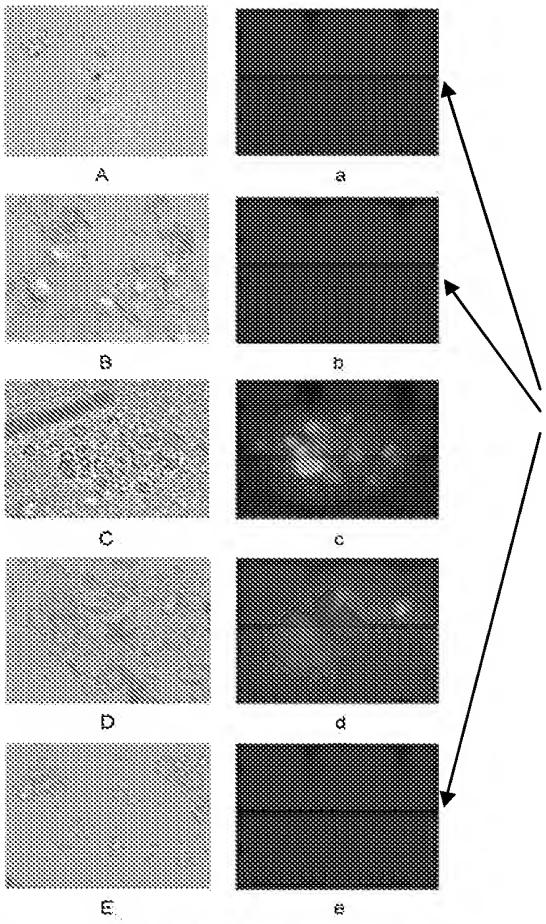
> "Since the prior art one or more recombinant proteins, VP28, VP24, VP26 or VP19 are the same as Applicants', the capacity to bind to and block, inhibit or retard binding to viral receptors needed for WSSV infection in the gut of the animal is viewed as the intrinsic property inseparable from the prior art one or more recombinant proteins or peptides VP28, VP24, VP26, or VP19." See, page 10, lines 17-22, of the August 10, 2010 Office Action.

Thus, the Office claims that Sayres inherently includes the elements that are not disclosed expressly in the publication. The Office stated that "[t]he prior art product necessarily includes *all* of the elements of the instant claims." See, page 4, lines 9-10, of the August 10, 2010 Office Action. The Office relied on Sayre, which does not teach binding and blocking of viral receptors, as an anticipatory reference and stated that the proteins and peptides of Sayre inherently bind to and block viral receptors in the gut of the animal. The Office used Yi as extrinsic evidence in an attempt to show inherency.

Applicants disagree that Sayre in combination with the extrinsic evidence of Yi anticipates the current claims. Yi does not show that binding and blocking of viral receptors in the gut of an animal is inherent in the recombinant cells of Sayre. In fact, Yi indicates that the binding of VP28 to shrimp cells is dependent upon pH. Yi recites:

> **VP28 can bind to shrimp cells with pH dependence**. The assumption that VP28 can bind to the shrimp cells as an envelope protein is reasonable. This assumption was demonstrated using the chimeric protein VP28-EGFP as an indicator to detect the *in vitro* binding procedure. Interestingly, at pH 6.0, the fluorescence could easily be detected at 1 h post-adsorption in the VP28-EGFP-treated cells (Fig. 2c). However, at pH 7.0, VP28 was weakly bound to the shrimp cells (Fig. 2d). **In addition, no fluorescence was detected in the cells at other pHs (Fig. 2a, b and e).** This indicates that the binding of VP28 to the cells is pH dependent and pH 6.0 is the suitable binding condition. See, page 728, col. 2, lines 18 – 29, of Yi (emphasis added).

Figure 2 is reproduced here for your convenience:



No fluorescence means that the **VP28-EGFP chimeric protein did not bind to the shrimp cells** at pH 4, 5, or 8.

Fig. 2. VP28-EGFP chimeric protein binding to the shrimp cells is pH dependent. After being treated at different pH, a binding assay of the VP28 -EGFP to shrimp cells was performed. a, b, c, d and e (Right) show images of the VP28-EGFP/cells treated at pH 4.0 8.0, the cells were examined by phase contrast microscopy under a 488 nm excitation wavelength. A, B, C, D and E (Left) were the glass photograph corresponds to the right.

As recognized by the Examiner and recited in the MPEP: "The fact that a certain result or characteristic may occur is not sufficient to establish the inherency of that result or characteristic. . . . To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." See, MPEP §2112IV, quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (internal quotation marks omitted).

Yi, therefore, does not indicate that VP28 proteins necessarily bind to shrimp cells when consumed. The binding is pH dependent and there is a narrow range of pH where the binding occurs. While there is a possibility that binding will happen at an appropriate pH, **possibilities and the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency**.

As Sayre does not disclose proteins or peptides that bind to and block viral receptors needed for WSSV or TSV infection in the gut of an animal, and Yi does not indicate that consumption of VP28 **necessarily** results in binding of the protein or peptide to viral receptors in the gut of the animal because of pH dependence, it is submitted that the instantly claimed invention cannot be anticipated by Sayre. Sayre does not disclose each and every element of the instant claims and the missing elements are not inherently present.

In light of the above discussion, applicants request the withdrawal of all anticipation rejections.

Rejection under 35 U.S.C. §103(a)

Claim 34 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kyle '638 or Sayre in view of Nakamura. Applicants insist that the proposed combination does not in any way establish a *prima facie* case of obviousness.

As previously stated, Kyle '638 is not considered to be competent prior art, and the Sayre reference does not teach or suggest all the claim elements of the presently claimed invention. The addition of Nakamura does not overcome the shortcomings of the Sayre reference.

There is nothing in the Sayre reference that would infer the binding to and blocking of viral receptors. The Court's decision in *In re Spormann,* 150 USPQ 449 (CCPA 1966), bears directly on point:

> "The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown"

Hence, obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert,* 28 USPQ2d 1955 (Fed. Cir. 1993). Here the binding and blocking of the viral receptors was unknown. Therefore, how could a skilled artisan make any modification while arriving at an invention that possesses the heretofore unknown

characteristic. While it is possible that, serendipitously, the invention would have such a feature, serendipity is not a valid basis for asserting obviousness.

As such, the proposed combination does not defeat the patentability of the presently claimed invention and applicants request the withdrawal of this obviousness rejection.

Rejoinder of Method Claims

When an application as originally filed discloses a product and the process for making and/or using such product, and only the claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product for examination through rejoinder procedure in accordance with MPEP §821.04, provided that the process claims depend from or include all the limitations of the allowed product claims.

The currently pending method claims include all the limitations of the product claims and meet all standards of enablement, written description, and definiteness under 35 U.S.C. §112. Accordingly, the method claims are in form suitable for future examination upon their rejoinder with the allowed product elected claims. Applicants are requesting that all method claims be rejoined, examined, and found allowable.

Fees Payable

No fees are believed due at this time. If any fee is found due for entry of this amendment, the Commissioner is authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen.

Conclusion

Applicants have satisfied all the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Devi reconsider the patentability of pending claims in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. If any issues remain outstanding incident to the prosecution of the application, Examiner Devi is requested to contact the undersigned attorney at (919) 286-8000.

Respectfully submitted,

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